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EXAMINER

DEMILLE, DANTON D

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 6/17/5

Application Number: 08/354,450
Filing Date: 12 December 1994
Appellant(s): Gary Karlin Michelson, M.D.

MAILED

JUL 01 2005

Group 3700

Todd M. Martin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20 April 2005.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

| | | |
|-----------|-----------------|---------|
| 5,261,914 | Warren | 11-1993 |
| 4,976,715 | Bays et al. | 12-1990 |
| 4,548,202 | Duncan | 10-1985 |
| 4,728,238 | Chisholm et al. | 03-1988 |

| | | |
|-----------|----------|---------|
| 4,422,276 | Paravano | 12-1983 |
| 4,338,835 | Simons | 7-1982 |

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The amendment filed 07 January 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the claims it is recited that

- a) said flexible member being at least in part curved
- b) said flexible member is deformable to have an at least in part concave shape
- c) said flexible member has a greater surface area to mass ratio than said shaft
- d) said flexible member has a smaller mass than the mass of said shaft
- e) at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees
- f) at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft
- g) at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

Regarding a), appellant is attempting to claim how the flexible member deforms during use as a positive structural limitation of the device when not in use. The claims recite "said flexible member being at least in part curved when said flexible member is in contact with the tissue" (claim 29 lines 10-11 for example). It is not clear how much weight can be given this

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language since this curved shape is not disclosed. Does that mean the flexible member is formed in part curved in order to be curved when in contact with tissue? Is it made out of a specific material that provides this function. Appellant is now relying patentability on limitation however, it is not clear from the specification what would comprehend this language. It is not clear how this would define over the art since the art teaches the same structure using the same material.

The same would apply to issue b). Requiring “said flexible member is deformable to have an at least in part concave shape” (claim 33, for example) is a limitation that requires a specific shape however, it is not clear how much weight to give this language since it is not disclosed.

Regarding c), appellant is claiming “said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member” (claim 34, for example). Appellant has also provided some detailed calculations on how they came up with this claim language. It is not clear how much weight can be given this claim limitation since it is not disclosed in the written description. Appellant is basing these detailed limitations from the drawings however, the drawings are not drawn to scale. Such detailed measurements and calculations cannot be clearly ascertained to such a detailed degree.

Regarding d), while the drawing may support that fact that the flexible member is smaller than the shaft (claim 35, for example), there is no support in the written description for this limitation and why it is now critical to the patentability of the invention. This function of being

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absorbed prior to the shaft so that the flexible member does not separate from the shaft is not fully understood because it is not disclosed.

Regarding e), claim 145, for example, recites “at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees.” This time this limitation is not contingent on when the device is in use. This is a positive structural limitation of the device before use. There is nothing in the written description clearly setting forth this claim limitation and the drawings do not support this. Appellant points to figure 7 to provide support for this limitation however, this drawing shows an intended use where the device is inserted at an angle into the tissue. What if the intended use was not inserted at an angle but rather at right angles to the tissue surface? Then the bottom surface of the flexible member would not have an included angle less than 90 degrees. Then would this limitation not exist if the intended use included being inserted at a right angle to the tissue? Moreover, this is the only limitation in a dependent claim. How does this claim further limit the parent claim? What further structural limitation is now being recited that somehow further limits the structure already recited? The parent claim 144 recites the first portion of the flexible member forms an included angle greater than 90 degrees that likewise is not contingent on when the device is in use. Likewise this limitation is not supported by the disclosure as originally filed.

Regarding f), the same argument above for e) would apply to the language of claim 211 for example, “at least a first portion of the said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft”. The bottom of “a member” is

not formed at an acute angle relative to the axis of the shaft as disclosed. It may form the angle in intended use however, that is contingent on how it is used.

Regarding g), the same argument above for e) would apply to the language of claim 211, for example, “at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft”.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There appears to be no support in the specification for the above noted claim language or the criticality why this is now being claimed.

Claims 29-300 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29-300 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds of the claims are since the claim language noted above has no clear support in the specification as originally filed. For example, it is not clear how much weight can be given the language that the flexible member forms an acute angle relative to the longitudinal axis of the shaft since the device is not made that way. There is no

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disclosure for the flexible head member being formed at an acute angle to the shaft. The angle the flexible head makes with the shaft is dependent on how it is placed in the body.

Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, 300 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren.

Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of flexible projections extending from said shaft and the flexible head member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion (column 6, lines 1-6). Warren teaches the heart of appellant's invention.

The claimed curvature, concave shape, acute angle, obtuse angle that the flexible head makes describes how it deforms during use. The thickness of the Warren's head is approximately 0.069 inches, column 3, line 38. Such a thin head would allow the flexible member to flex during use. Moreover, Warren teaches column 6, lines 46-49, "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." The only difference between the claims and Warren would appear to be dimensions or sizes of the different parts and how it flexes during use. Due to the fact that the rivet of Warren has all of the basic main structural features and is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that the rivet of Warren would comprehend the claimed resilient characteristic as disclosed. The head of

Warren would appear to be flexible to conform to the shape of the tissue to which it is being forced into.

Appellant appears to be attempting to define the instant invention over the prior art by claiming how the rivet is deformed during use. Warren teaches that the specific dimensions and sizes of the different parts of the rivet can be modified to fit a particular intended use. There appears to be no unobviousness to change the dimensions of the rivet to find the optimum characteristics for a particular intended use. As suggested by Warren different dimensions can be used dependent on practical considerations of intended use. Making the head of the fastener less obtrusive so that it is flush with the tissue surface so that the head does not interfere with any surrounding tissue is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation. To any extent it is felt that the head of Warren is not flexible to conform to the shape of the surrounding tissue, it would have been obvious to one of ordinary skill in the art to modify Warren to change dimensions of the flexible member to reduce the amount of material used or reduce the size of the flexible head to make it less obtrusive.

Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, 256-300 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. in view of Warren.

Bays teaches another fastener that has all of the claimed structure including being made out of the same material as the instant invention and intended to repair torn meniscus tissue. For

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the same reasons above, it is not clear how the claimed invention would define over Bays other than how it deforms during use. The thickness of the Bays flexible head member is 0.025 inches. Even thinner than Warren's. Bays also teaches "It is to be understood, of course, that variations from these dimensions are possible for different utilizations of the tack member 10" column 7, lines 15-17. It would appear that the head of Bays would curve or flex when the rivet is pressed against the tissue to deform to match the same shape of the tissue at least to some extent. As noted above, the specific dimensions of the rivet are well within the realm of the artisan of ordinary skill. It would appear that the flexible member of Bays would result in a flexible head member that would flex and conform to the shape of the tissue as it is being forced into to the tissue. To any extent it is felt that the head of Bays is not flexible, it would have been obvious to one of ordinary skill in the art to modify Bays to find the optimum dimensions as also suggested by Warren to providing a flexible head to make the head less obtrusive and more flexible so that it is flush with the surrounding tissue.

Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above and further in view of Duncan, Chisholm et al. or Paravano.

There is no unobviousness to the specific shape or number of ribs on the shaft of the rivet. Both Bays and Warren teach that the specific configuration of the ribs is well within the artisan of ordinary skill. Warren teaches column 7, lines 3+ "that surgical fastener 100 might be formed with more or less ribs 135 than the three ribs shown in FIGS. 1-8. Thus, for example, a surgical fastener 100A having eight ribs 135A is shown in FIGS. 9-11." Bays teaches column 4, lines 62-64, "As few as one and more than three barb members may be provided within the scope

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of the present invention, so long as the barb member or members provide sufficient resistance to rearward movement of the shaft portion through the cartilaginous tissue.” Duncan, Chisholm and Paravano are all cited to show different conventional alternative arrangements of ribs on the shafts of fasteners. Duncan teaches a surgical fastener that has barbs that are spaced in plural arrays around the axis of the shaft. Chisholm and Paravano also exemplify the art of providing plural arrays of barbs or fins spaced around the axis of the shaft. It would have been obvious to one of ordinary skill in the art to further modify the prior art to arrange the ribs, fins or barbs in arrays around the axis of the shaft as taught by Duncan, Chisholm or Paravano to provide the desired level of anchorage for the fastener to hold it in place.

Claims 87, 88, 131, 132 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Simons.

There appears to be no unobviousness to exactly how the rivet interfaces with the driving element. Any conventional configuration to interface the driving element with the head of the rivet would have been obvious. The problem of keeping the engagement between the driving element and the rivet is old. The driving element merely has to drive the rivet into the bone and keep engagement with the rivet. Warren teaches a hollow driver 600 that butts the end of the rivet to force the rivet into the hole in the bone. Bays teaches a driver that includes a shaft that mates with a passageway within the rivet. There is no unobviousness to how the driver forces the rivet into the bone. Simons teaches another equivalent way for the driver to mate with the head of the fastener. The fastener includes a generally spherical recess in the head. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a

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spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.

(11) *Response to Argument*

Regarding the issue of new matter under paragraph a) above, Appellant argues that the instant invention is flexible and thereby has disclosed the claimed limitation of “being at least in part curved when said flexible member is in contact with the tissue”. Appellant is arguing that this limitation defines over the prior art because of the prior art relative sizes shown in the drawings are not the same dimensions shown in the drawings of the instant application. In order to interpret the scope of the claimed invention one has to look toward the specification to find the breadth and meaning of the language used in the claims. In order to find how the claimed flexible head member defines over the flexible head member of the prior art one has to look to the specification of the instant invention. Is this curved flexible member a result of what the flexible head is made out of? Is it specific dimensions. The specification appears silent with regard to how one is to know how the instant invention is different from the prior art. The prior art teaches all of the positive structural limitations including the type of material used. But somehow the prior art head is different from the instant invention head. It can't be because of the type of material used because they are both made out of the same material. The thickness of the head of Warren is 0.069 inches and the thickness of the head of Bays is 0.025 inches. How much thinner would the head of the prior art have to be in order to anticipate the claimed invention? How exactly is the prior art different from the instant invention? It is not clear from the specification exactly what structural limitation provides this curved surface when in use.

Reciting that it is curved when it is in contact with the tissue is something that happens during use however, if the location of implantation happens to be on a flat section of tissue then the head would not deform so then how would one know if the invention in their hand anticipates the claimed invention?

Regarding paragraph b), Appellant argues that the flexible member is “deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant’s disclosure as originally filed.” As noted above it is not clear what structural limitation or characteristic of the disclosed invention the claimed limitation is referring to since the prior art teaches everything claimed. Particularly since this language is found in a dependent claim 33 further limiting the curved shape recited in claim 29. What further limitation from the curved shape provides this added limitation that makes it concave? Moreover, this is the only limitation in the dependent claim so it is not clear how this claim further defines the invention as set forth in claim 29. What new or additional feature over what has already been claimed does this new claim provide? The specification doesn’t appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Regarding paragraph c), Appellant is now reciting a specific structural relationship “wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member”. There is no support in the invention as disclosed for such a limitation. Appellant is relying on the drawings to provide support for this feature. Appellant argues that it may be sufficient to show possession of an invention by disclosure of drawings that are sufficiently detailed to show

that Appellant was in possession of the claimed invention as a whole. This is generally true for structure or elements sufficiently detailed to show possession of the claimed invention however, it is the examiner's position that the details that Appellant is now relying patentability on are of such minor differences that the drawings cannot be relied upon to teach the patentable limitation. The differences are a matter of degree and not the overall existence of structure. This is not a matter of whether or not the drawings show a claimed element but rather mathematical calculation of relative dimensions based on drawings that are not drawn to scale. If this limitation is of such critical importance that patentability depends on such a limitation, why doesn't the written description provide at least a hint of such a limitation?

Regarding paragraph d), the same arguments above for extracting dimensions from the drawings would apply here as well.

Regarding paragraph e), the limitation that a second portion of the bottom of the flexible member forms an included angle relative to the mid-longitudinal axis of the shaft is greater than 90 degrees in claim 145 is not contingent on when the flexible member is in contact with tissue. Therefore this is a positive structural limitation of the device before use. This is clearly not supported by the specification as originally filed. Appellant relies on figure 7 to support this claim however, this figure shows the device when inserted at an angle in the tissue. The flexible member does not naturally form this included angle. It is only in intended use and only when the device is being inserted at an angle to the surface of the tissue. According to these claims, if the device were inserted at a right angle to the surface of the tissue then the flexible member would be at an angle to the surface of the tissue when in contact with the tissue. The flexible member would not be flush with the surface of the tissue.

Regarding paragraphs f) and g), the same argument above in paragraph e) would apply here as well. The claimed acute and obtuse angle the member makes relative to the shaft is not contingent on intended use and would appear to be inaccurate since the device as disclosed does not have this limitation naturally. Only in intended use does this angle exist however, these claims require this angle as a positive structural limitation.

Regarding the objection to the specification under 35 U.S.C. 112 first paragraph, the examiner respectfully submits that the objection to the specification is proper in view of the arguments given above.

Regarding the rejection of claims 29-300 under 35 U.S.C. 112 first paragraph as containing subject matter that is not adequately supported by a clear and complete disclosure is proper in view of the arguments give above.

Appellant states that the examiner has not provided any rationale as to why claims 60-64, 67-99, 144, 146, 147, 151-182, 186-210, 242-244 and 248-292 are rejected under 35 U.S.C. 112 first paragraph. These claims also contain the offensive language and fall within the paragraphs above. For example, claim 60 is an independent claim that recites the flexible member being at least in part concave when said flexible member is in contact with the tissue and therefore falls with paragraph b) above. Claims 61-64 and 67-99 depend on claim 60 and therefore include all the limitations of claim 60 and likewise not supported by a clear and complete disclosure. Claim 144 recites at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees and therefore falls with paragraph e) above.

Regarding claims 29-59 and 100-143 concerning the phrase “said flexible member being at least in part curved”, Appellant argues that during use the flexible member will flex and conform to the shape of the tissue. This is all well and good however, this does not further limit the structure of the rivet itself. Applicant is basing patentability on one specific intended use and one specific location. The device is not limited to use in one specific situation. There may be a situation that requires the rivet to be inserted at right angles to the tissue and therefore it is not clear how the claims would define over the prior art in this instance because the flexible member would have flexed.

Regarding claims 33, 105, 148, 183, 214, and 245, the same arguments above would apply here as well. It is not clear how much weight can be given the functional intended use claim language.

Regarding claims 34, 65, 106, 149, 184, 215 and 246, as noted above the drawings are not drawn to scale, therefore it is not clear how much weight can be given these detailed measurements drawn from them.

Regarding claims 35, 66, 107, 150, 185, 216 and 247, the same arguments of the drawings are not drawn to scale as noted above would apply here as well.

Regarding claim 145, the same arguments above given to functional intended use language applies here as well.

Regarding claims 211-241, the same arguments above given to functional intended use language applies here as well.

Regarding the rejection of claims 29-300 under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Appellant regards as the invention. Since the claims recite claim language that is not clearly supported by the specification with sufficiency to determine the scope of the claim, the claims are vague and indefinite.

Appellant's arguments under paragraph IV subparagraphs A-C are moot in view of the amendment entered in 20 September 2004.

Regarding Appellant's arguments under paragraph V subparagraph A1, contrary to Appellant's assertion that the examiner is focusing only on the material of the Warren fastener to teach the claimed invention, the examiner is instead relying on the full disclosure of Warren to provide the heart of Appellant's invention. Not only does Warren teaches all of the positive structural limitations of the rivet including a shaft, a truncated conical penetration leading end, a flexible member at the trailing end and a plurality of flexible projections extending radially from the shaft but it is also made of the same material. The only difference is whether or not the flexible member being at least in part curved when the flexible member is in contact with the tissue. It is not clear how much weight can be given this claim language since it contingent on intended use of the device. This limitation is only true when the flexible member is in contact with the human tissue. Plus this limitation is also contingent on whether or not the rivet is being inserted at an angle to the tissue surface. Should the rivet be inserted at right angles to the tissue surface then the flexible member would not curve, be concave or have an included angle other than 90 degrees. The flexible member would stay in its natural form of being perpendicular to the shaft.

Regarding Appellant's arguments that the dimensions of Warren would preclude flexing of the head of Warren, the thickness of the head of Warren is 0.069 inches. It is obvious to one

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of ordinary skill in the art that a head that is only 0.069 inches in thickness would allow the head to flex and conform to the shape of the surface of the tissue.

Moreover Warren teaches that the dimensions of the fastener can be changed to make the fastener thinner or thicker. It can be longer or shorter. Warren is not limited to just the embodiment shown in the drawings. Finding the optimum dimensions and characteristics for a specific intended use would be well within the realm of the artisan of ordinary skill. Making the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation. If it is felt that the head of Warren would not conform to the shape of the tissue then it would have been obvious to one of ordinary skill in the art to modify Warren to change dimensions of the fastener such as to reduce the amount of material used or to reduce the size of the flexible head to make it less obtrusive.

It is not clear what specific limitations would have to be taught in order to anticipate the functional intended use language claimed. The only difference between the prior art and the perceived claim limitations is specific dimensions of the flexible head member. If 0.069 inches is not thin enough to be flexible then what dimension would be? There appears to be no unobviousness to finding the optimum size and dimensions of the prior art device for a specific intended use as suggested by the prior art. Moreover, there doesn't appear to be unexpected results which is different in kind and not merely in degree from the results of the prior art.

Regarding Appellant's arguments under paragraph V subparagraph A2, Appellant states that Warren teaches that the head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone and that the instant invention is not pounded into place. The instant invention is also intended to be used to attach soft tissue to bone (page 4, lines 29-30) therefore it is not clear what the difference is. If the prior art and the instant invention are intended for the same purpose then how is it different? Appellant is again arguing over how the device is intended to be used. Appellant's specification may not recite that it is pounded into place however it is connected to a driver and driven into place some how. The prior art is also driven into place using the same type of driver.

Regarding Appellant's arguments under paragraph V subparagraph A3, Appellant argues that the examiner's redesign of Warren is without teaching or suggestion. Warren already teaches the thickness of the head is only 0.069 inches which would result in a head that would be flexible. This inherent flexibility would comprehend the claim language. However, to any extent it is felt that the head of Warren is not flexible enough the examiner is using the teaching of the prior art to modify the dimensions of the fastener if needed. It is not clear if Warren even needs to be modified however, if it does Warren himself teaches such a modification. Column 6, lines 47-49, of Warren teaches that the dimensions of the fastener can be changed as desired. Making the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. If necessary reducing the size of the head as much as possible to make the head less obtrusive would have been an obvious provision.

Regarding Appellant's arguments under paragraph V subparagraph A4, Appellant argues that the examiner is using impermissible hindsight. As noted in the paragraph above, it is believed that the head of Warren already is flexible however, it would have been obvious to modify Warren to change the dimensions of the head or shaft for any desired specific intended use as taught by Warren. The modification is not impermissible hindsight. The prior art suggests such changes may be necessary.

Regarding Appellant's arguments under paragraph V subparagraph B1, Appellant argues that the head of Warren is repeatedly struck in order to drive fastener 100 through the tissue into bone. Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone. Even though Appellant has extrapolated the relative dimensions of the thickness of the head in relation to the thickness of the shank wall and recited the use of fillet 161 it still doesn't preclude one of ordinary skill in the art to vary the dimensions of the head and shank as desired and still be able to drive the fastener into bone. The driver of Warren provides the required structural rigidity to facilitate driving and inserting the fastener into bone. The driver supports the entire outer surface of the head and provides the required structural support to the head to drive the fastener into the bone. The shaft of the driver received within the hollow shank of the fastener also provides the required structural rigidity to the shank to maintain the integrity of the shank to drive the fastener into the bone.

Appellant's arguments that if Warren's head were modified to be thinner than the thickness of the shank it would destroy the fastener are unsupported. The driver provides the required stability to the fastener to withstand the forces applied to insert the fastener to the bone. If Appellant's arguments were true the Appellant's invention wouldn't work either because the

instant invention is also intended to be inserted into bone just as Warren's. Appellant's invention is "to provide a device which can be used generally to attach soft tissue to bone" page 4 lines 29-30.

Regarding Appellant's arguments in paragraph V subparagraphs B2, B4, B6, the claims require that the outer edge of the flexible member be beveled. Warren already teaches this limitation as shown in the drawings. The outer edge of the flexible member is rounded or beveled as shown in the drawings.

Regarding Appellant's arguments in paragraph V subparagraph B3, B5, B7, B8, B10, B11, B12, B13, B14 the same reasons recited above regarding the flexibility of the head of Warren would apply here as well. The head would conform to the shape of the tissue to some extent including being concave if the shape of the tissue is concave.

Regarding Appellant's arguments in paragraph V subparagraph B9, Duncan teaches the plurality of projections in radially staggered configuration as claimed and would have been an obvious provision in Warren. There is no unobviousness to the exact shape of the projections as long as they prevent removal of the fastener.

Regarding Appellant's arguments in paragraph VI subparagraph A1, Appellant states that there is no suggestion to modify Bays to change the dimensions of the device. The examiner respectfully disagrees since Bays teaches "It is to be understood, of course, that variations from these dimensions are possible for different utilizations of tack member 10". The prior art teaches the motivation for modifying the dimensions of the rivet. Different intended uses requires appropriate changes to the dimensions of the rivet. It is not inventive to discover the optimum or

workable ranges by routine experimentation. There are no unexpected results by changing the dimensions of the rivet as noted above.

Bays teaches the thickness of the head is 0.025 inches which is smaller than the thickness of the head of Warren. How thin does the head have to be to anticipate the claimed invention?

Regarding Appellant's arguments in paragraph VI A2, it is not clear how much weight can be given the arguments that the applicator 20 of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. This has nothing to do with the rejection. The claims do not define over the applicator 20 of Bays. Bays is not being modified regarding the applicator 20. Warren is merely cited to teach the same thing that Bays already teaches i.e., that variations in the dimensions of the rivets is well known to the artisan of ordinary skill. The only difference between the claims and Bays is Appellant's arguments of how the device deforms during use. It is maintained that the prior art devices would deform during use and if it is felt that the rivet of Bays somehow does not deform then Warren additionally is cited to teach the convention of being able to change the relative dimensions of the rivet dependent on practical considerations of intended use.

Regarding Appellant's arguments in paragraph VI subparagraph B1, as noted above the heads of Bays and Warren can withstand being inserted by the insertion tool because the insertion tool contacts and holds the head of the fastener firmly in place and transfers the forces directly to the shaft of the fastener just as Appellant's invention does. The head also still has the ability to conform to the shape of the tissue because of the sizes and any variation of size is well within the realm of the artisan of ordinary skill.

Regarding Appellant's arguments in paragraph VI subparagraph B2, B4, B6, the outer edge of head of Bays is also rounded or beveled comprehending the claim limitations.

Regarding Appellant's arguments in paragraph VI subparagraph B3, B5, B7, B8, B9, B10, B11, B14, B18, the same arguments give above in item V(B)(1) would apply here as well.

Regarding Appellant's arguments in paragraph VI subparagraph B12, B15, B19, Appellant argues that the prior art does not teach driving the rivet until the face of the driving instrument contacts the top of the member. It is not clear how Appellant can disregard the teaching of the prior art. Figure 1 of Bays clearly shows the driving instrument in contact with the top of the member. Figure 7 of Warren clearly teaches the driving instrument in contact with the top of the member.

Regarding Appellant's arguments in paragraph VI subparagraph B13, B17, B20, and claims 281, 291 attaching the meniscus to the bone isn't always inserting the leading end of the shaft toward the center of the knee. Repairing torn meniscus is never always going to be directed toward the center of the knee.

Regarding Appellant's arguments in paragraph VI subparagraph B16, the fastener of Bays is friction fit within the J-shaped arms 26 of the insertion member. There is no unobviousness to the head being friction fit or snap fit in place. Such is well within the realm of the artisan of ordinary skill.

Regarding claims 277, 286-288, 295, the rivet passageway cooperating with the shaft extending from the handle of the insertion instrument is clearly taught by both Bays and Warren and as noted in the previous paragraph. The rejection is maintained.

Regarding Appellant's arguments in paragraph VII subparagraph A, the references to Chisholm and Paravano are cited to teach different shapes and arrangements of the projecting members. In the art of providing projecting members along the shaft of fasteners to solve the problem of holding the fastener in place preventing inadvertent removal is the same across different arts. Both Warren and Bays teach that the number and location of the projections on their fasteners can be varied dependent on intended use. Someone solving the problem of finding other equivalent alternative configurations of the projecting members to prevent the fastener from coming out of the hole would look to other fasteners not necessarily restricted to the medical art.

Bays and Warren already teach projections that are spaced apart from one another along the mid-longitudinal axis of said shaft. Duncan, which is in the medical field, teaches projections that are spaced apart along and around the mid-longitudinal axis of the shaft. The projections are in at least four arrays along and around the shaft. They are radially staggered at 90 degree intervals.

Regarding Appellant's arguments in paragraph VII subparagraph B1, B2, B3, B4, B5, B6, B7, Duncan teaches projections that are in staggered overlapping configuration as they overlap each other along the longitudinal axis of the shaft and are staggered at 90 degree intervals around the shaft. To any extent appellant's projections are staggered so are the projections of Duncan. Appellant's drawings do not appear to show any configuration that is different from what Duncan shows.

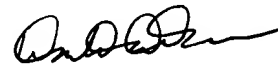
Regarding Appellant's arguments in paragraph VIII subparagraph A, B1-B4, Simons teaches a depression in the trailing end of the fastener to mate with the corresponding shaped end

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of the insertion member. Simons refers to the depression as "a substantially spherical surface" column 2, lines 62-63. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent alternative way of mating the driver to the fastener. In the art of engaging the driver to the head of the fastener one would look to equivalent driver and fastener engagement means. Simons exemplifies an obvious equivalent.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Danton DeMille
Primary Examiner
Art Unit 3764

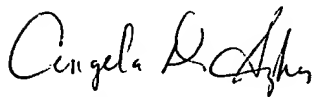
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